EXHIBIT B

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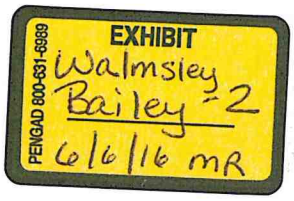

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2327

2 : 12-md-02327

THIS DOCUMENT RELATES TO:

HON.
JOSEPH R. GOODWIN

Pamela Bailey, et al. v. Ethicon, Inc.., et al No. 2:12-cv-00878

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MI)

My name is Konstantin Walmsley. I have been retained by the Motley Rice Law Firm to give medical opinions related to Pamela Bailey. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including the pubovaginal sling. I have

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attending training provided by Ethicon, Inc. regarding the TVT device. I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining Pamela Bailey:

- WellStar Windy Hill Hospital;
- Emory University Hospital;
- Georgia Regional Urology;
- The Emory Clinic;
- Harbin Clinic;
- Cartersville Family Medicine;
- Social Security Administration;
- Centers for Medicare and Medicaid Services (Region 4) Medicare Part A & B;
- WellStar Kennestone Hospital;
- Aetna US Healthcare;
- Ed Voyles Honda;
- Wal-Mart Stores Inc;
- Promina Windy Hill Hospital;

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- Windy Hill Anesthesia Associates, PC
- Piedmont OB/Gyn;
- Georgia Bone & Joint Surgeons, P.C.;
- Cartersville Medical Center;
- Charles J. Sidlow, DPM;
- Urban Family Practice Associates;
- Piedmont Mountainside Hospital;
- Summit Radiology Services P.C.;
- Belk Human Resources Department;
- Cartersville Heights Care;
- Humana Inc.;
- Kroger Pharmacy Corporate RQ;
- Coosa Diagnostic Center;
- Harbin Clinic Catersville Family Practice;
- Atlanta Breast Care;
- Cartersville Internal Medicine;
- PT Solutions;
- LabCorp of America;
- Wellstar Cobb Women's Center;
- Align Networks;

In addition to the review of the medical records listed above, I performed an independent medical examination of Pamela Bailey on May 3rd, 2016. I have also reviewed the following medical literature and other TVM related documents and have relied, in part, on the documents below in addition to my medical and clinical experience in forming my opinions:

- AMA 8.08
- TvT Instructions for Use
- C.G. Nilsson et al "Seventeen years' follow-up of the tension free vaginal tape procedure for female stress urinary incontinence." Int. Urogynecol. J. (2013) 24:1265-69
- P. Hilton "A clinical and urodynamic study comparing the Stamey bladder neck suspension and suburethral sling procedures in

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treatment of genuine stress incontinence" British Journal of Obst. & Gynecol (February 1989, Vol 96, pp. 213-220

- H. Enzelsberger et. al "Comparison of Burch and Lyodura Sling Procedures for Repair of Unsucessful Incontinence Surgery" Obstet & Gynecol, Vol 88, No. 2, August 1996
- A.S. Arunkalaivanan et al "Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire based study" Int. Urogynecol J (2003), 14: 17-23
- K. Guerrero et al "A randomized controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up" Int. Urogynecol J (2007) 18:1263-1270
- B. Welk et al, "Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontience" JAMA Surgery, Published Online September 9, 2015.
- E. Petri et al., "Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification" Fur. J. of Obstet. & Gynecol. and Reprod. Bio. 165 (2010) 347-351
- B. Klosterhalfen et al., "Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair" Biomaterials (1998) 2235-46
- J. Anger et al., "Complications of Sling Surgery Among Female Medical Beneficiaries" Obstet. & Gynecol. Vol. 109, No. 3 (March 2007)
- P. Moalli et al, "Tensile Properties of five commonly used mid-urethral sling relative to the TVT" Int. Urogynecol J (2008) 19:655-663
- A. Clave et al, "Polypropylene as a reinfomrcement in pelvic surgery is not inert: comparative analysis of 100 explants" Int. Urogynecol J (2010) 21:261-270
- 0. Chinthakanan et al., "Mesh Removal Following Sling/Mesh Placement: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-139-40

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- 0. Chinthakanan et al, "Indication and Surgical Treatment of MidUrethral Sling Complications: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-142-43
- E. Petri et al., "Comparison of late complications in retropubic and transobturator slings in stress urinary incontinence" Int. Urogynecol. J. (2012) 23:321-325
- S. Abbott et al., "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study" American J. of Obset. & Gynecol (February 2014) 163.e1-8.
- 0. Agnew et al, "Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence" Int. Urogynecol J. (2014) 25:235-239
- J. Duckett et al, "Pain after suburethral sling insertion for urinary stress incontinence" Int. Urogynecol J. (2013) 24:195-201
- C. Skala et al., "The IUGA/ICS classification of complications of prosthesis and graft insertion" Int. Urogynecol J (2011) 22:1429-1435

- Ashok, E. P. (2012). Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification. European Journal of Obstetrics & Gynecology and Reproductive Biology (2012) 347-351.

- K. Svabik et al., "Ultrasound appearances after mesh implantation — evidence of mesh contraction or folding?" Int. Urogynecol J. (2011) 22:529-533
- A. Rogowski et al., "Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair" Int. Urogynecol. J. (2013) 24:2087-2092

Clinical History

- On April 19th, 2001, Mrs. Bailey underwent a retropubic TVT sling insertion by Dr. David Perlow. The procedure was uneventful. Dr.

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Hill memorializes using curved Metzenbaum scissors as a spacer between the sling and the urethra to ensure tension-free placement.

- On May 3rd, 2003, she presented to Dr. Kate Osterloh with complaints of worsening urinary incontinence. She stated that her bladder was leaking all of the time and she had to change her clothes and pads multiple times per day. She has failed a bladder tack in 2001 and a collagen injection, which only gave her improvement for 3 months. She denied dysuria or hematuria at that time.

- On December 3rd, 2004, Mrs. Bailey presented to Dr. Christopher Sward with complaints of dysuria, incontinence, dyspareunia, urinary frequency, and hematuria.

- On February 2", 2005, Mrs. Bailey saw Dr. Rony Adam secondary to urinary incontinence. He memorialized her history of anterior compartment prolapse, status post previous surgery with a mesh sling in 2001, followed by collagen injections. She reported leaking with standing and bending to sit down. She did not particularly notice leaking with coughing or sneezing. She stated that she leaked usually without warning. She denied any significant urgency however she did report frequent urination and also had a problem with complete emptying of the bladder and difficulty initiating her voids as well as a slow stream. She reported nocturia 2 to 3 times per night, wearing pads for most of the day. She denied any pressure symptoms but she does report difficulty during intercourse. She stated her partner can feel something inside the vagina. She denied any excessive consumption of caffeine or coffee. She reported no improvement after her first surgery in 2001, After her collagen injection treatment in 2000, she did report some improvement for only 2 months. She previously tried Ditropan and Detrol LA and she stated that these medications did not help her. More recently, the doctor who saw her thought that the mesh from her previous surgery may have caused some erosion and she was told that she had blood present in the urine. Physical exam demonstrated that her vagina was scarred anteriorly, no discharge was present however there was an odor. Mesh erosion was noted at the mid-urethra on the right side with tenderness elicited. She was noted to have a cystocele present with a palpable transverse defect as well as a mild rectocele. Her levator ani were normal.

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- On March 30th, 2005, Mrs. Bailey had urodynamics performed by Dr. Adam demonstrating bladder outlet obstruction with a detrusor pressure at Q max of 70 cm H2O and a high residual. The cystometrogram also showed detrusor overactivity but with no motor urge incontinence and no stress incontinence documented.

- On June 20th, 2005, because of bladder outlet obstruction, dyspareunia, and persistent mesh erosion Mrs. Bailey underwent cystoscopy and partial mesh excision by Dr. Rony Adam. Dr. Adam memorialized that the TVT mesh was located about 1 centimeter proximal to the urethral meatus and was causing significant urethral compression. She was discharged the following day performing clean intermittent catheterization because of incomplete bladder emptying. Pathologic examination of the removed tissue revealed a 30 mm x 11 mm x 5mm piece of mesh with attached soft tissue described as fibromuscular tissue.

- On July 14th, 2005, she returned to Dr. Adam's office. She reported painful urges to urinate and reported that she was still leaking occasionally. Postoperatively she was doing self intermittent catheterization for approximately two weeks, but it became too painful for her to continue. She had a urinary tract infection two weeks post-operatively which was treated with antibiotics. She had a post-void residual of 10 cc and was started on Oxybutynin for urgency and urgency urinary incontinence.

Methodology

My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

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General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures — including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2001 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices

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of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina and peri-vaginal tissues persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. These events were reported in the mid-urethral sling literature prior to when Mrs. Bailey was implanted. In my opinion, a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2001 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.

In 2001, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Bailey was unable to receive proper informed consent relating to this safer alternative because of the lack of

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information in the TVT IFU inherent to the risks of using synthetic mesh. As such, Dr. Perlow was unable to warn Mrs. Bailey of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Mrs. Bailey suffered vaginal sling erosion, contraction and scar plate formation as a result of the physical properties of the TVT device. These conditions are documented in the medical records.

Mrs. Bailey's vaginal sling erosion was caused by retraction and shrinkage of the mesh. Recognized causes of sling erosion include: (1) a surgical error in implantation technique; (2) atrophy of the vaginal tissue surrounding the device; and (3) changes to the physical properties of the device post-implantation including, but not limited to, retraction, shrinkage, fraying, roping and curling.

A surgical technique error can be reasonably excluded as a cause of the erosion. Dr. Perlow's operative dictation indicates he placed the sling in a tension-free manner and Mrs. Bailey's complications were not caused by an over tensioning of the device. Further, Mrs. Bailey had no evidence of obstructive voiding symptoms immediately following sling implantation further confirmin proper tension-free sling placement by Dr. Perlow.

Atrophy of the surrounding tissue can reasonably be excluded as a cause of the exposure as Mrs. Bailey was pre-menopausal at the time of her sling surgery and had no evidence of vaginal atrophy.

Based on the foregoing analysis, and based on my education, training, experience and knowledge, it is my opinion to a reasonable degree of medical probability the cause of Mrs. Bailey's sling erosion was contraction of the TVT device. This is supported not only by Dr. Adam's recognition of the sling significantly compressing the urethra at the time of partial mesh excision but also by her gradual development of bladder outlet obstruction which occurred years after placement of the sling. This supports the fact that the mesh contracted over time as opposed to the sling being placed with tension at the time of initial implant.

A. Erosion.

Mrs. Bailey developed signs and symptoms consistent with mesh erosion that were confirmed by Dr. Adam's physical examination, performed on February 2nd, 2005. 1 have observed erosions of suburethral slings and other forms of transvaginal mesh in my clinical practice.

B. Contraction/Shrinkage

Mrs. Bailey's TVT contracted post implantation. Dr. Adam documented such during his surgery noting that the TVT mesh was causing significant urethral compression at the time of partial mesh excision. This represents a clear distinction compared to Dr. Perlow's tension-free placement of this same mesh performed in his 2001 surgery.

I have observed compressive pieces of transvaginal mesh in my clinical practice that are the result of post-implantation contraction or shrinkage of the mesh.

C. Scar Plate

During his physical examination of Mrs. Bailey, Dr. Adam confirmed that there was vaginal scar along her anterior vaginal wall. This was also confirmed during my independent medical examination of Mrs. Bailey

have observed scar plate formation in patients such as Mrs. Bailey who have had TVT slings implanted.

Case Specific Opinion No. 2

Mrs. Bailey's vaginal pain and dyspareunia was caused by contraction of the TVT device, and scar plate formation. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury (7) lichen sclerosis ; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

I am able to rule in erosion as a cause of Mrs. Bailey's dyspareunia in 2005. Her complaints as well as Dr. Adam's physical examination in 2005 support this conclusion.

I am able to rule in contraction and scarring as potential causes of Mrs. Bailey's vaginal pain and dyspareunia. These conditions are documented in the medical records of Dr. Adam as previously stated above. Furthermore, pain produced on palpation on exam enables me to rule in contraction and scarring as a potential causes of Mrs. Bailey's dyspareunia.

I am able to exclude paraurethral banding as a cause of Mrs. Bailey's dyspareunia and vaginal pain because I have seen no paraurethral banding documented.

I am able to exclude vestibulitis, and lichen sclerosis as causes of Mrs. Bailey's vaginal pain and dyspareunia.

Vaginal tissue atrophy is excludable as the cause of Mrs. Bailey's dyspareunia as she never was diagnosed with this condition and is pre-menopausal as well, making the likelihood of this condition practically impossible.

I am also able to exclude pelvic floor dysfunction as the cause of Mrs. Bailey's dyspareunia. The absence of documented tenderness to the pelvic floor musculature by multiple consultants during multiple examinations enables me to reasonably exclude pelvic floor dysfunction as a potential cause of Mrs. Bailey's dyspareunia.

Case Specific Opinion No. 3

Mrs. Bailey continues to have dyspareunia presently. As part of my expert review and preparation of my opinion regarding Ms. Manor, I performed an independent medical exam of this patient on May 3rd , 2016. At that time, the patient reported several bothersome symptoms including voiding dysfunction and dyspareunia. Her voiding dysfunction consisted of straining to void, urinary frequency, and incomplete bladder emptying. She described having been sexually active every day but now having intercourse3-4 times per year. She described pain with intercourse for both her and her husband. She described her pain as being located at the top of her vagina near the introitus. Her husband described feeling a sticking/scratching sensation on the left side of his penis

during intercourse and expressed guilt over attempting intercourse as it was no longer enjoyable for his wife.

On physical exam, there was notable tenderness upon palpation along the right peri-urethral area where there was induration consistent with scar or possible residual mesh underneath fibrosed vaginal tissue. Thus was a physical exam finding consistent with the complaints put forth by Mr. and Mrs. Bailey.

As part of the foreign body reaction to synthetic mesh the periurethral, perivesical, and vaginal tissues create dense fibrotic scar tissue which compromises the elasticity and compliance of these tissues. As such, when patients present with complications from synthetic mesh slings, they tend to develop a combination of voiding dysfunction, sometimes manifest as obstructive in nature, sometimes combined urinary incontinence that is often both stress incontinence in combination with urgency urinary incontinence. This relates to a combination of factors, one being the development of non-compliant "pipestem" urethral tissues that are unable to coapt and therefore hold urine; the second factor relates to a combination of (I) inflammation rendering the bladder muscle (or detrusor muscle) unstable, as well as (2) scarring of the bladder muscle adjacent to the synthetic mesh foreign body response, in which the bladder muscle's ability to contract is compromised because of scarring and fibrosis. Although Mrs Bailey, does not suffer from incontinence presently, she does have obstructive voiding symptoms including starining to void, incomplete bladder emptying, and urinary frequency, which can occur in the setting of incomplete bladder emptying.

Case Specific Opinion No. 4

Ms. Bailey's future prognosis as it relates to her vaginal pain, dyspareunia, and voiding dysfunction is guarded. Because she has pelvic mesh still inside of her body, she will continue to suffer from vaginal pain and dyspareunia. Moreover, she has pelvic tenderness and residual scar tissue in the area where her mesh erosion was treated. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. I anticipate that if heroic surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure. Although these interventions could be somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from.

With regards to her dyspareunia, her symptoms might be ameliorated with sling removal. Once again, this would be a heroic procedure performed in a tertiary academic center and would likely create further fibrosis and scarring which would more likely than not result in persistent dyspareunia. In summary, within a reasonable degree of medical certainty, the voiding dysfunction, vaginal pain, and dyspareunia will be a lifelong condition for this patient.

Sincerely,

Konstantin Walmsley, M.D.